Message

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Sent: 4/2/2019 4:34:18 PM
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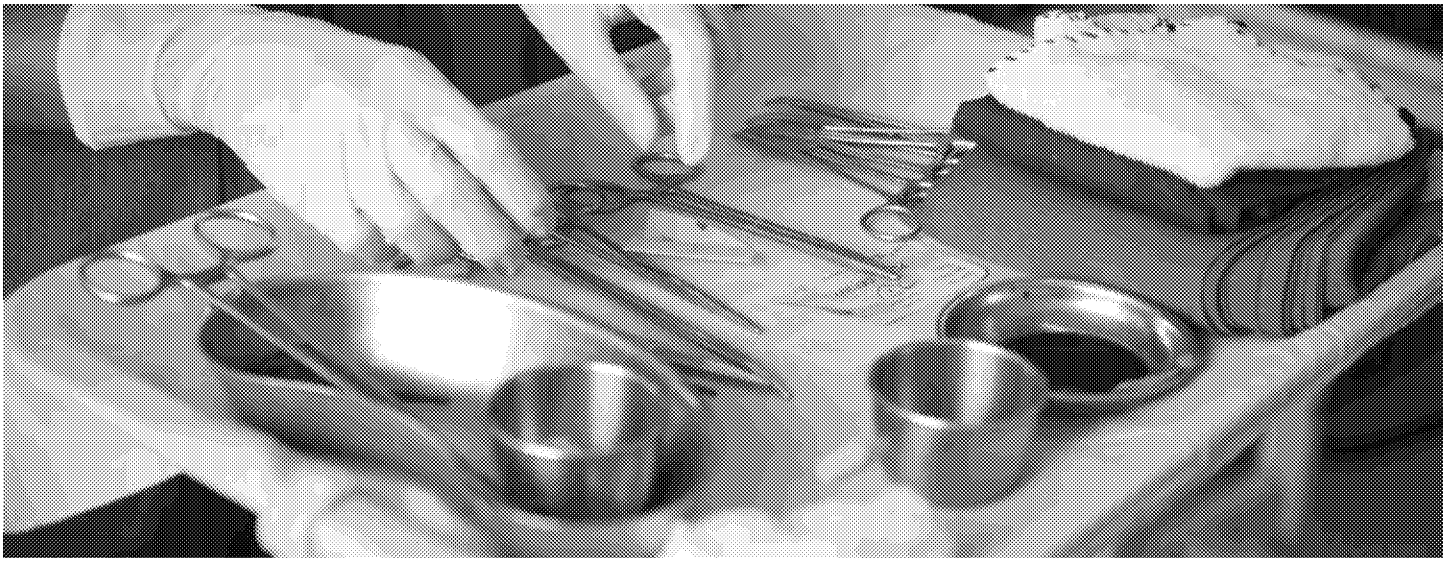

A nurse prepares surgical tools ahead of an operation in a photo taken on August 18, 2015.
NICOLAS ASFOURI/AFP/Getty Images

News

Dirty Devices Await FDA Alternative to Cancer-Causing Sterilizer

Posted April 2, 2019, 5:36 AM

- Lawmakers push FDA for ethylene oxide substitute
- FDA said hospitals could clean products with gas sterilizer in 2015

Dirty stents, needles, and medical mesh need a new sterilizer because companies that use a common—but cancer-causing—cleaner keep closing. However, the FDA's options may be limited.

More than half of all medical supplies are disinfected with ethylene oxide (EtO), a colorless, odorless gas that the EPA has labeled a carcinogen. The chemical is facing new scrutiny after elevated ethylene oxide emissions from Sterigenics U.S. LLC's Willowbrook, Ill., facility prompted outrage from local residents and the state's senators.

Sterigenics ultimately closed the facility in February, and Viant Medical Inc., a Michigan-based sterilizer that also uses ethylene oxide, will also shut its doors later this year. Sterigenics and Viant Medical clean over 600 medical products, according to the FDA.

That's left the Food and Drug Administration scrambling for alternatives, but the instruments that are sterilized with the gas are very specific, Lawrence Muscarella, a hospital safety consultant who has written extensively about the problems of cleaning and sterilizing endoscopes and other medical devices, said.

"If we use a different sterilization technology, at least one perceived to be safer, we want to ensure we're not damaging the instrument, which could cause no net gain and harm to patients," he said.

FDA Considering Options

The FDA issued a four-step plan March 26 intended to settle any disruption from the closings and help device makers transition to other sterilization sites. It includes a new ethylene oxide resources webpage and a device shortage inbox for makers, patients, and organizations to tell them if products become scarce. The agency still plans to discuss the possibility of alternatives for this type of sterilization later this year.

The American Chemistry Council, a chemical industry trade association, said it isn't aware of any proven alternate to ethylene oxide.

The options need to be scientifically evaluated and not driven by political winds, Muscarella said.

"It's also fair to ask where were all of these discussions five years or 10 years ago?" he said. "FDA has approved and promoted EtO gas in the past, so now if we plan to mitigate its use, let's do so with objective science using safe technologies that address all concerns, including cost-effectiveness, sterilization efficacy, and material compatibility, as well as environmental. I want everyone to be safe."

The American Hospital Association declined to comment.

Too much exposure to ethylene oxide over time has been linked to breast cancer, non-Hodgkin lymphoma, lymphocytic leukemia, brain damage, and difficulty breathing, according to the Environmental Protection Agency's 2016 Integrated Risk Information System (IRIS) report, which describes the health effects of chemical exposure.

More Monitoring, Alternatives

Illinois Sens. Tammy Duckworth (D) and Dick Durbin (D) told Bloomberg Law they've encouraged the FDA to seek alternatives to ethylene oxide.

Medline Industries, another medical product sterilizer, said it uses many methods of sterilization, including gamma radiation, e-beam, dry heat, and terminal steam sterilization. These methods aren't necessarily the best for low-heat specific devices.

In the meantime, Duckworth and Durbin want the EPA to expand its ethylene oxide monitoring to other sites that use the gas in Illinois.

"Results of the EPA's air quality monitoring confirmed that high levels of ethylene oxide were being emitted by Sterigenics, posing a significant public health threat to the people of Willowbrook and the surrounding communities," they said in a March 29 statement.

The Illinois EPA turned down a similar request from Kristina Kovarik, the mayor of Gurnee, Ill., earlier this month.

"The [FDA] recognizes that sterile medical devices are critical for preventing infections and ensuring patients have safe surgeries and medical treatments, and, crucially, that a large number of medical device types cannot be sterilized without the use of ethylene oxide," the Advanced Medical Technology Association said.

https://news.bloombergenvironment.com/environment-and-energy/dirty-devices-await-fda-alternative-to-cancer-causing-sterilizer

CHEMICAL WATCH ARTICLES

Country Focus: Industry sees USMCA as chance to prod Mexican chemical management

Trade deal could be North American model for the chemical sector

29 March 2019 / GHS, Mexico, Substance notification & inventories, TSCA

Mexico's pending trade deal with the US and Canada could provide a North American model for the chemical sector.

Mexico's chemical regulation is amorphous, run by a hodge-podge of internal departments — health, environment, agriculture, energy — with no overarching law like TSCA or REACH.

So, when Mexico began renegotiating the North American Free Trade Agreement (Nafta), Mexico's trade partners in the US were eager to influence the country's regulation scheme.

'This is an opportunity to shape what could be a chemical management regime formation effort in Mexico'

"This is an opportunity to shape what could be a chemical management regime formation effort in Mexico in the future," said Ed Brzytwa, director for international trade at the American Chemistry Council (ACC).

The resulting document – the US-Mexico-Canada Agreement (USMCA) – contains a sectoral annex on chemical substances that was absent in the original Nafta. It promotes a risk-based approach to regulation, directing the three countries to align their risk assessment and management measures within their legal frameworks.

Chemical industry groups in the US (ACC), Mexico (ANIQ) and Canada (CIAC) all coordinated in writing the annex and applauded its inclusion.

However, the enthusiasm of ACC and CIAC about a Mexican "regime" on the horizon might be premature. Guillermo Miller Suárez, vice president of information and international trade for ANIQ, said that the chemical annex is simply a regulatory cooperation document, not an indication of something more.

"That doesn't mean that we will in the near future – or even eventually – adopt any North American[-style] regulations. I don't see that happening anytime soon."

A starting point?

But Mr Brzytwa said the annex, and the significant industry discussion that prompted its inclusion, could be a starting point for Mexico and for the development of a North American model of chemical regulation.

"These provisions of the USMCA are not creating a chemical management regime in Mexico; they are guideposts," he said in an interview with Chemical Watch. "So if Mexico does move in that direction, they will have a stronger foundation now."

 Despite Mexico's uncertainty over chemical regulation – made all the more so by a self-described "revolutionary" president who took office in December – the ACC describes the USMCA as an opportunity to encourage Mexico to build a broader regulatory framework in the US's image.

"We were in constant communication with ANIQ," said Mr Brzytwa. "They know that their government could be taking steps to build a chemical management regime and they felt that having these provisions in the USMCA was an important starting point."

Mexico's chemical exports are valued at $2.36bn per year, according to 2017 figures from Mexico's National Institute of Statistics and Geography.

Much of Mexico's chemical regulation is in the hands of the environment ministry (Semarnat) and specifically the climate change institute (Inecc, which is within Semarnat), but the country does not have one agency or regulation that governs the sector.

"Chemicals are managed by many different agencies [with] many different approaches" but none of these are harmonised, said Nidia Calvo, the Americas chemical regulatory compliance programme manager at Hewlett-Packard.

Background to USMCA

The final version of USMCA – which has yet to be ratified – is the result of almost two years of negotiation by industry groups.

In a 2017 joint statement by the ACC, ANIQ and CIAC, the Nafta revision was described as an opportunity for a North American model in contrast to the "hazard-based approaches rising elsewhere".

And, in the final draft, industry wishes have been largely granted. It has essentially formalized aligning the risk-based approach to regulation that all three countries already used – while Mexico does not have a TSCA or a CMP, existing laws in Mexico already regulate individual chemicals based on risk rather than hazard.

Other potential areas of cooperation include:

- implementation of the UN Globally Harmonized System (GHS) of classifying and labelling of chemicals;
- coordination of safety data sheets and how confidential business information (CBI) is relayed;
- compatibility of chemical inventories;
- coordination on chemical risk assessment and risk management methodologies, tools, and models, and on the development of specific chemical assessments; and
- scientific criteria and data sharing.

The ACC's Greg Skelton told the US trade representative that the revision could be a chance to extend the TSCA and Canadian Chemicals Management Plan (CMP) models to Mexico. However, the industry's Mexican counterpart does not necessarily agree.

"As far as I know, there are no whispers of this [within the government]," said ANIQ's Mr Miller.

Changes to the Mexican status quo

USMCA is not the only factor driving change in Mexico's chemical sector.

Mexico previously had duel labelling and safety data sheet requirements to meet domestic and international requirements. However, ANIQ, which represents 95% of Mexico's chemical manufacturers, requested the voluntary option of using the GHS system as an alternative in 2011. The mandatory fifth revision of the GHS standard came into force in October 2018.

Also in autumn, Mexico catalogued its chemical substances with information from producers and importers, which will be updated regularly by Inecc. The effort prioritises using a single nomenclature for identifying substances.

Despite the massive effort of cataloguing chemicals, there has not been a high level of interest in the chemical sector, either in Enrique Peña Nieto's administration, which oversaw the endeavour, or in the new president's, Ms Calvo said. There also isn't a lot of information about chemical management available from Semarnat or Inecc, the two main organisms in charge of the sector, she adds.

The Obrador variable

Mexico's leftist president Andres Manuel López Obrador took office on 1 December 2018, promising "revolution" after decades of corruption and deteriorating trust in the government.

USMCA was signed by all parties on 30 November, just one day before Mr Obrador became president. But Rodrigo Favela, a partner at HCX, a consulting firm in Mexico City, said the president was very involved in its negotiation: no changes to the agreement are expected to come from his office.

Some argue his involvement in the negotiations illustrates the new president's desire to have a hand in every change in Mexico.

Mr Obrador "wants to have control over everything," said Jeremy Martin, vice president for energy and sustainability at the Institute of the Americas.

However, the new president has specifically highlighted environmental sustainability as a priority for his administration, which is compatible with the priorities put forth by USMCA.

> *'We view having a sound chemical management regime as a way to improve the environment and foster more sustainable practices around chemicals'*

"We view having a sound chemical management regime as a way to improve the environment and foster more sustainable practices around chemicals," said Mr Brzytwa.

Wildcards

The ACC and others fear that the Canadian and US governments may prove to be even bigger wildcards than Mexico's new president in the long run, however.


Canadian prime minister Justin Trudeau must hold a federal election by 21 October and government officials have said anger over US steel and aluminum tariffs could prevent Canada from ratifying USMCA. Speaking at the ACC's recent GlobalChem conference, Scott Thurlow, an independent lobbyist who formerly worked for CIAC, said it is not even clear if the USMCA will be introduced in this Parliament.

In fact, he continued, "there is a convention in Canada that we will not introduce a trade measure before it has been ratified by its partners."

But ratification in the US is also not guaranteed. Democrats took control of the House of Representatives in November, expressing concerns about insufficient labour and environmental provisions in the trade deal.
Meanwhile, US president Donald Trump has threatened to pull out of Nafta in order to pressure Mexico and Canada into either choosing between the new trade deal or the pre-Nafta conditions.

Mr Brzytwa called a potential early withdrawal "a difficult proposition for many members of Congress, and for industry for that matter".

Industry on both sides of the US-Mexico border accept that ratifying USMCA will take time and effort. But just having the text of the deal – especially one that reflects the regulatory alignment the ACC, ANIQ and CIAC have pushed for – gives them a starting point for discussion.

"We are able as an industry to talk very openly about the contents of that text," said Mr Brzytwa, and that conversation is "another opportunity to acclimate these Mexican officials to the North American, risk-based model."

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Lisa Martine Jenkins

Americas reporter

Related Articles

- Nafta talks offer chance of 'risk-based' regulation in Mexico, says ACC
- Risk-based chemicals management approach promoted in new Nafta

- Mexico adopts voluntary GHS standard
- Mexico's mandatory GHS standard comes into force
- Mexico begins work on catalogue of chemical substances
- North American trade deal backs risk-based approach to chemicals regulation
- US midterms trigger leadership shifts for chemical legislation

Further Information:

- USMCA
- Catalogue of chemicals in commerce
- Joint statement by ACC, CIAC and ANIQ on Nafta
- USMCA sectoral annexes

Experts urge voluntary data submission to support TSCA evaluations, prioritisation

EPA flags up exposure information needs to industry

2 April 2019 / Data, TSCA, United States

The US EPA has cautioned that, in the absence of industry providing it with high quality data, it will need to use conservative assumptions in its prioritisation and risk evaluation of chemicals under TSCA. And a range of experts at a recent conference has joined the agency in urging industry to voluntarily submit information – in particular, exposure data – to support these efforts.

Speaking at last month's GlobalChem conference in Washington DC, EPA's Joel Wolf said the agency needs to learn about the manufacturing, processing, distribution, use and disposal of substances to support its efforts to prioritiseand then evaluate them.

And he said that while the agency relies on such information sources as the TSCA chemical data reporting (CDR) rule, the toxics release inventory (TRI) and data from state and federal agencies, he also emphasised the importance of voluntary industry submissions.

"The better the information we have, obviously the higher quality and the less conservative assumptions that get built into any decisions that we make," said Mr Wolf, who is chief of the agency's existing chemicals programme.

Bill Greggs, an industry consultant, agreed that without key information the "EPA really only has one option: and that option is to take a conservative approach."

"That's not a good thing, I don't think, for your chemical or for your chemical use," he told industry attendees.

Regarding the types of information that are most essential, Martha Marrepese, a partner at Wiley Rein, identified exposure data as the biggest gap.

"We're really in great shape, in general, on the tox side," she said. "But where we really need to go is [to] dig a little deeper, in all of our work, on the exposure side."

Successfully generating such information, she said, "will be a tremendous contribution of this [the TSCA] programme, and it will also make the outcomes of the programme be much more predictable and reasonable," she said.

"Risk evaluations involve complex decisions that we have to make," agreed the EPA's Mr Wolf. "The more comprehensive the exposure information, the most informative [it will be] to the work that we're going to do."

Mr Wolf acknowledged that substances in articles can prove difficult for industry, particularly when a company might import an article and not know what it contains.

"We recognise these challenges, but we still need to get an understanding of the chemicals in various articles and products, so we continue to try to figure out new ways to engage in that area," he said.

The American Chemistry Council's Steve Risotto agreed, saying that "use and exposure may be the most critical part of the evaluation."

Consortia

To support these efforts, experts have recommended that industry work to form consortia and generate data the agency needs.

"I want to encourage industry to provide data voluntarily to EPA for these exercises, especially exposure data," said Ms Marrapese. "I think that consortia – dedicated consortia, downstream consortia – for exposure data collection is going to be critical."

Mr Risotto added that, when the EPA designates a substance as high priority, it has probably already determined that it has enough hazard information to form the basis of an assessment. Additional data, he said, needs to come early in the process.

"If there's more data that you want to provide, provide it quickly. If there's more research that you want to do, start it now," he said. "The sooner that you can get that information in to the agency for evaluation, the better off you will be, the more likely that will be incorporated into the draft evaluation."

Bill Griggs agreed: "Given the statutory deadlines, today may not be too soon to get started" with data gathering and consortia-building.

Related Articles

- EPA names priority candidates for TSCA evaluations

EU to add HEPB to list of allowed cosmetics preservatives

2 April 2019 / Cosmetic products Regulation, Europe, New substances, Personal care

The European Commission has notified the WTO of a proposed amendment to the cosmetics Regulation to authorise use of the preservative hydroxyethoxyphenyl butanone (HEPB).

It notified the WTO on 28 March of a draft Regulation to amend Annex V – the list of preservatives allowed in cosmetics products, which currently contains 59 substances.

The proposed authorisation of HEPB is for rinse off-, oral care and leave-on cosmetic products at a maximum concentration of 0.7%. It follows the final Opinion of the EU's Scientific Committee on Consumer Safety (SCCS) in March.

The Commission plans to adopt the amendment in the fourth quarter of the year.

Related Articles

- EU publishes Opinion on HEPB in cosmetics

- **Further Information:**

- WTO notification
- Annex V

EU amends CLP Regulation to GHS revisions

2 April 2019 / CLP Regulation, Europe, GHS

The European Commission has amended Annexes I to VI of the CLP Regulation to take account of the sixth and seventh revised editions of the Globally Harmonized System (GHS) of classifying and labelling of chemicals.

Among the changes are a new hazard class for desensitised explosives and a new hazard category, pyrophoric gases, within the hazard class flammable gases. Others include adaptations to:

- the criteria for substances and mixtures which in contact with water emit flammable gases, the generic cut-off values;
- the general provisions to classify aerosol forms of mixtures; and
- the detail of the definitions and classification criteria as appropriate for the hazard classes explosives, flammable gases, flammable liquids, flammable solids, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory and skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity and aspiration hazard.

Some amendments are also introduced to some hazard and precautionary statements.

The Regulation enters into force on the twentieth day following its publication in the EU's *Official Journal*.
It applies from 17 October 2020. Application is deferred to ensure that suppliers of substances and mixtures have time to adapt to the amended provisions, but can apply them earlier voluntarily.

Further Information:

- Text of Regulation

Echa begins consultation on microplastics restriction proposal

2 April 2019 / Alternatives assessment & substitution, Europe, Microplastics, REACH

Echa has started the public consultation on its restriction proposal for intentionally added microplastics in products.

The consultation is open until 20 September, but the agency has encouraged early submissions to make it easier for its committees to consider responses.

Echa published the proposal on 30 January, after a request by the European Commission a year earlier for a REACH Annex XV restriction dossier for microplastics. The request forms part of the EU plastics strategy.

The restriction dossier provides a wide-ranging definition. Microplastics are described as solid-polymer-containing particles, to which additives or other substances may have been added, and where at least 1% w/w of particles have:

- all dimensions 1nm ≤ *x* ≤ 5mm; or
- for fibres, a length of 3nm ≤ *x* ≤ 15mm and a length to diameter ratio of >3.

It proposes to ban certain consumer and professional uses of intentionally added microplastics, while other uses would be subject to labelling/information requirements and annual reporting.

Multiple applications are covered, including in agriculture, horticulture, cosmetics, paints, coatings, detergents, maintenance products, medical and pharmaceutical applications, and oil and gas sectors.

Echa's Risk Assessment (Rac) and Socio-economic Analysis (Seac) Committees and the Enforcement Forumwill now scrutinise the proposal.
The committees are expected to send their opinions to the Commission in spring 2020. It is then up to the Commission to propose to amend the REACH Regulation if the restriction meets the legal requirements.

Related Articles

- Echa outlines proposed microplastics restriction measures
- EU enforcers to prioritise evaluation decisions

- **Further Information:**

- Public consultation

Efsa study looks at emerging chemical risks in food chain

2 April 2019 / Europe, Food & drink, Food contact, REACH, Substances of concern

The European Food Safety Authority has published a study on identifying potential emerging chemical risks in the food chain from substances registered under REACH.

It performed in-depth evaluations for ten potential emerging risks that so far have not been assessed by an EU regulatory body for their presence in food via the investigated exposure pathway.

The procedure was previously developed and tested in an Efsa-sponsored pilot study.

Substances were selected that:

- had a full registration under REACH;
- met eligibility criteria, for example availability of a Cas number; and
- were considered to be inside the applicability domain of the models used in this study (excluding, for example, ionisable compounds and metals).

This selection reduced the number from about 15,000 to 2,336 substances that were then assessed in four blocks. These were:

- environmental releases (based on tonnage and use pattern);
- biodegradation (using BioWin predictions assessed in a battery approach);
- bioaccumulation in food/feed (using ACC-HUMANsteady modelling); and
- toxicity (based on classification for carcinogenicity, mutagenicity, reprotoxicity and repeated dose toxicity).

An evaluation of both approaches led to the prioritisation of substances for their potential to represent emerging chemical risks in the food chain.

From a list of 267 priority substances 55 substances were excluded. The remaining 212 are considered to:

- be released to the environment and/or poorly biodegraded;
- bioaccumulate in food/feed; and
- represent a chronic human health hazard.

The study established a link between a chronic health hazard and possible exposure of humans via the food chain. For the majority of the 212 priority substances, such a link has not been previously recognised, it said.

The fact that ten were selected for in-depth evaluation does not imply that the remaining 202 potential emerging risks are of lower priority, it said.

Further Information:

- Abstract
- Final report

OTHER ARTICLES

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... use to make decisions about how to prevent and reduce exposures to harmful or **toxic substances**. The relationship between the amount of chemical ...

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